

REMARKS

Objections to the Claims

Claims 2-11 allegedly do not further limit the claims. Applicants respectfully disagree.

The Office Action alleges that the features recited in claim 2 do not impart any physical or otherwise material property to the composition that is not already present in the composition recited in claim 1. However, this is not true either for the original claims or the even clearer version thereof submitted above.

Claim 1, and all dependent claims from it are directed to a pharmaceutical “combination” and not to a “composition.” Additionally, the recited feature, for example, from claim 2 that “said earlier period is the time before about 1:00 pm of a given day and said later period is the time thereafter” specifically imparts a physical characteristic to the combination, i.e., the physical embodiment of the combination under claim 2 is required to provide the release profile to satisfy the claimed feature in question. The physical characteristics of the combination itself will determine the release characteristics of the combination. The situation with the other dependent claims is analogous.

Claim 20 is amended to depend on claim 16 as suggested by the Examiner.

Claim 28 has also been further clarified.

Objections to the Specification

The Office Action alleges incorporation of essential material in the specification by reference to a foreign application or patent is improper. However, WO 00/23055 does not contain essential material. This reference is cited to provide general information about amphetamines, as is clear on page 1 of the specification.

The specification is amended to capitalize trademarks and well-known generic terminology is inserted to accompany each, taken from the PDR cited at page 1. See amendment to paragraph starting on page 1, line 6.

The hyperlink from page 32 is removed.

Claim Rejections Under 35 USC § 112, second paragraph

Claims are rejected as allegedly omitting essential elements to the claimed release

profile. Applicants respectfully disagree with this rejection, but, as indicated above, have amended independent claims 1 and 16 to further clarify them.

Claims 4, 10, 12, 20 and 25 are rejected as allegedly indefinite because of the appearance of the term “about” therein. Many cases, contrary to this allegation, hold that this term is not indefinite. See *Modine Mfg. Co. v. U.S. Intern. Trade Comm'n*, 75 F.3d 1545, 1554 [37 USPQ2d 1609] (Fed. Cir. 1996) (“Although it is rarely feasible to attach a precise limit to ‘about’ the usage can usually be understood in light of the technology embodied in the invention.”), cert. denied, 518 U.S. 1005 (1996); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1557 [220 USPQ 303] (Fed. Cir. 1983) (descriptive term “about,” when used to describe ranges in a patent, does not render a claim indefinite), cert. denied, 469 U.S. 851 (1984); *CPC International Inc. v. Archer Daniels Midland Co.*, 831 F. Supp. 1091, 1110 [30 USPQ2d 1427] (D. Del. 1993) (“In the context of determining an appropriate tip speed for a particular vessel and agitator, a person skilled in the art would not find the term ‘about 600 cm/sec’ to be unclear.”), aff’d, 31 F.3d 1176 (Fed. Cir. 1994), cert. denied, 513 U.S. 1184 (1995); *Zoltek Corp.*, 48 Fed.Cl. at 300 (“The Court does not agree with Defendant’s contention that a precise limit must always be attached to the term ‘about.’”); *Syntex (U.S.A.), Inc. v. Paragon Optical Inc.*, 7 U.S.P.Q.2d 1001, 1038 (D. Ariz. 1987) (“‘About’ is not broad or arbitrary but rather is a flexible term with a meaning similar to ‘approximately.’”). One of ordinary skill in the art would understand the scope of the claims. Thus, there is no indefiniteness.

Claim Rejections Under 35 USC § 102

These rejections are moot in view of the clarifying amendments to the claims, which were incorrectly interpreted in the Office Action to only require that amphetamine in base and/or salt form be present without regard to the recited release profile of the combination.

Claim Rejections Under 35 USC § 103

Various recited features of certain claims are alleged to be obvious over the combination of several references, but not a single specific allegation is made of the obviousness of the recited feature of the independent claims that each of the l- and d-amphetamines are “adapted for release such that” the recited timing of the release profile is achieved. Thus, for this reason alone, the burden on the PTO to establish a case of prima

facie obviousness has not been met.

The Office Action alleges that the doses claimed are obvious. While determination of doses alone over a prior art reference may in some circumstances be considered determination of an optimum result effective variable, such is not applicable here. The recited release profile changes the pharmaceutical combination itself in a way not taught or suggested in the prior art.

The Office Action cites WO '998 and alleges that this reference provides motivation for providing more l isomer than d isomer, which is not admitted. However, nothing in this reference (nor is it alleged) teaches or suggests the claimed feature recited above, that the combination provides for a release profile where a higher ratio of l to d isomers is achieved in a time period later in the day than at a time period earlier in the day. Nothing about the timing of the claimed varying ratios is taught or suggested in the reference. As the Office Action admits, this reference merely teaches the use of a composition enriched for the l-enantiomer. One of ordinary skill in the art could at best have been motivated on the basis of this teaching to administer the same enriched composition at all times, i.e., the same composition earlier and later in the day, thereby not meeting or suggesting the claimed combination.

The Office Action also alleges that it would have been within the purview of the skilled artisan to employ any one or more of the special release formulations of the prior art, for example, immediate, pulse, controlled release, etc.. However, the prior art relied upon here does not teach or even suggest the specific above-recited release profile feature of the claims. The prior art relied on generically teaches various release profiles, but provides no information on the release profiles for the l and d isomers as claimed.

The Office Action also alleges that Patrick et al. teaches the use of dextroamphetamine only and also teaches ADDERALL[®], which was known to contain d- to l- amphetamines at ratio of 3:1. WO '998, discussed above, was cited for the use of a composition enriched in l-isomer. The Office Action then alleges that it would have been obvious to use a two-pronged regimen as it would have been prima facie obvious to use in combination two or more agents that have previously been used separately for the same purpose.

However, even assuming one of ordinary skill in the art would be motivated to use together any two compositions known for the treatment of the same thing, nothing in the prior art teaches or suggests achieving the timing aspect of the release profile as claimed herein.

Merely picking and putting together elements of the prior art from various references to form the claimed invention is not adequate for establishing a prima facie case of obviousness. The question is not whether the references can be combined in a way which would render an invention obvious, but rather whether there is motivation in the prior art for such a combination. See, e.g., *In re Laskowski*, 871 F.2d 115, 10 USPQ2d 1397 (Fed. Cir. 1989). In the present case there is no motivation in the prior art for a combination achieving a molar ratio of l-amphetamine to d-amphetamine released from the combination in a time period later in the day which is higher than said ratio released therefrom in a time period earlier in the day.


Reconsideration is respectfully requested.

Obviousness Type Double Patenting Rejections

Applicants will address these rejections after allowable matter has been identified.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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Filed: December 5, 2005

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